

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Express Mail No.: EV 570 176 507 US

Date of Deposit: 2 May 2005

Application No.: 10/511,718

International
Filing Date: 16 April 2003

Applicant: LIU, Jun, et al.

Title: TUBERCULOSIS VACCINES INCLUDING RECOMBINANT
BCG STRAINS EXPRESSING ALANINE DEHYDROGENASE,
SERINE DEHYDRATASE AND/OR GLUTAMINE
SYNTHETASE

Attorney Docket: 9896-000053/NP

RECEIVED

3 JAN 2006

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Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

Legal Staff
International Division

EXPRESS MAIL TRANSMITTAL

The following papers are being deposited with the United States Postal Service Express Mail Post Office To Addressee on 2 May 2004 and addressed for receipt by the United States Patent and Trademark Office:

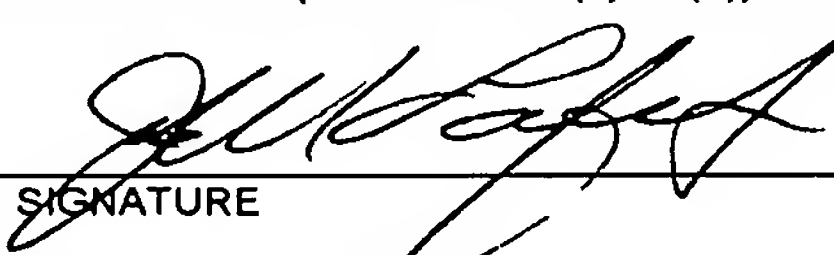
1. Express Mail Transmittal (Label No. EV 570 176 507 US);
2. PCT Transmittal Letter to the US Designated/Elected Office
Concerning a Filing Under 35 USC 371 (2 pages, in duplicate);
3. Signed Declaration and Power of Attorney (3 pages);
4. Computer Readable Form (CFR) of Sequence Listing on 3.5"
diskette;
5. Statement for Sequence Listing (1 page);
6. Copy of Notification of Missing Requirements (2 pages);
7. Return Postcard.

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 9896-000053/NP
INTERNATIONAL APPLICATION NO. PCT/CA03/00566		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/511,718
INTERNATIONAL FILING DATE 16 April 2003 (16.04.2003)		PRIORITY DATE CLAIMED 16 April 2002 (16.04.2002)
TITLE OF INVENTION Tuberculosis Vaccines Including Recombinant BCG Strains Expressing Alanine Dehydrogenase, Serine Dehydratase and/or Glutamine Synthetase		
APPLICANT(S) FOR DO/EO/US LIU, Jun; CHEN, Jeffrey and ALEXANDER, David		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: Express Mail Transmittal (Label EV 570 176 507 US); Statement Regarding Sequence Listing; copy of Notification of Missing Requirements; Return Postcard 		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/511,718		INTERNATIONAL APPLICATION NO. PCT/CA03/00566		ATTORNEY'S DOCKET NUMBER 9896-000053/NP	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee..... \$300				\$	
22. <input type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$100 All other situations..... \$200				\$	
23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500				\$	
TOTAL OF 21, 22 and 23 =				\$	0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	130.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					0.00
SUBTOTAL =				\$	130.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	0.00
TOTAL NATIONAL FEE =				\$	130.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	0.00
TOTAL FEES ENCLOSED =				\$	130.00
05/05/2005 SNAJARRO 00000062 080750 10511718 01 FC 1617 130.00 DA				Amount to be refunded:	\$
				Amount to be charged:	\$
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>08-0750</u> in the amount of \$ <u>130.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-0750</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO: Joseph M. LAFATA HARNESS, DICKEY & PIERCE, P.L.C. P. O. Box 828 Bloomfield Hills, MI 48303 United States of America				<div style="text-align: center;">  SIGNATURE Joseph M. LAFATA NAME </div>	
				37,166 REGISTRATION NUMBER May 2, 2005	

10/18/2004
M. Requirements
Due! 5-1-05



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

JML

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/511,718	Jun Liu	9896-000053/NP

INTERNATIONAL APPLICATION NO.

PCT/CA03/00566

LA. FILING DATE

PRIORITY DATE

04/16/2003

04/16/2002

27572

HARNES, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

CONFIRMATION NO. 4920

371 FORMALITIES LETTER



OC000000015244900

Date Mailed: 03/01/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 10/18/2004
- Copy of the International Search Report filed on 10/18/2004
- Preliminary Amendments filed on 10/18/2004
- Biochemical Sequence Listing filed on 10/18/2004
- U.S. Basic National Fees filed on 10/18/2004
- Priority Documents filed on 10/18/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- **\$130** Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$130** for a Large Entity:

- **\$130** Late oath or declaration Surcharge.

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with

the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e) and PCT Rule 13ter.1(a)(ii).
- APPLICANT MUST PROVIDE:
 - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
 - A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
 - For Rules Interpretation, call (703) 308-4216
 - To Purchase PatentIn Software, call (703) 306-2600
 - For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

KAREN R MCLEAN

Telephone: (703) 308-9140 EXT 214

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/511,718	PCT/CA03/00566	9896-000053/NP